111TH CONGRESS 1ST SESSION

S. 1778

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 14, 2009

Mrs. Shaheen (for herself and Mr. Vitter) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic drugs, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Access to Affordable
- 5 Medicines Act".
- 6 SEC. 2. LABELING CHANGES.
- 7 Section 505(j) of the Federal Food, Drug, and Cos-
- 8 metic Act (21 U.S.C. 355(j)) is amended by adding at the
- 9 end the following:

1	"(10) If the proposed labeling of a drug that is the
2	subject of an application under this subsection is different
3	from the labeling of the listed drug at the time the Sec
4	retary evaluates the application under this subsection, the
5	drug that is the subject of such application shall, notwith
6	standing any other provision of this Act, be eligible for
7	approval and shall not be considered misbranded under
8	section 502 if—
9	"(A) a revision to the labeling of the listed drug
10	has been approved by the Secretary within 60 days
11	of the expiration of the patent or exclusivity period
12	that otherwise prohibited the approval of the drug
13	under this subsection;
14	"(B) the Secretary has not determined the ap
15	plicable text of the labeling for the drug that is the
16	subject the application under this subsection at the
17	time of expiration of such patent or exclusivity pe
18	riod;
19	"(C) the labeling revision described under sub
20	paragraph (A) does not include a change to the
21	'Warnings' section of the labeling;
22	"(D) the Secretary does not deem that the con
23	tinued presence in commerce of the labeling of the

listed drug (as in effect before the revision described

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[under subparagraph ((A))	adversely	impacts	the	safe
2	use of the drug;					

"(E) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

"(F) such application otherwise meets the applicable requirements for approval under this subsection.".

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